OCT 11 2000 K002125

Section XII: 510(k) Summary of Safety and Effectiveness

SAFE MEDICAL DEVICES ACT OF 1990
510(k) Summary

NAME OF FIRM: Implant Resource, Inc.
AKA: Medical Products Resource
1166 East Cliff Rd.
Burnsville, MN. 55337

510(k) FIRM CONTACT: Al Lippincott
Engineering Consulting Services, Inc.
3150 E. 200th St.
Prior Lake, MN 55372

TRADE NAME: Pins and Wires

COMMON NAME: K-Wires, Steinman Pins, Calibrated Pins, Spinal Wires

CLASSIFICATION: PIN, FIXATION, SMOOTH (see 21 CRF, Sec. 888.3040)

PIN, FIXATION, THREADED (see 21 CRF, Sec. 888.3040)

IMPLANT, FIXATION DEVICE, SPINAL (see 21 CRF, Sec. 888.3060)

DEVICE PRODUCT CODE: HTY, JDW, JDN

SUBSTANTIALLY EQUIVALENT DEVICES: Zimmer Internal Fixation Systems
Depuy Internal Fixation Systems

DEVICE DESCRIPTION: Steinman Pins, Kirschner Wires, and Calibrated Pins are of various diameters, various points, threaded or smooth, and are in various lengths. Spinal wires are pliable to bend around rods, plates and bone and come in various lengths. All above pins and wires are made of 316LVM Stainless Steel to ASTM F 138 – 97.

INTENDED USE: Internal fixation pins and wires are temporary appliances and are utilized in skeletal traction for alignment of long bone fractures, as guide wires in hip pinning, and fracture alignment in certain other types of fractures. Spinal wire fixation is for securing hooks, rods, plates to the spinal spinous process in straightening spine curvature disorders.

BASIS OF SUBSTANTIAL EQUIVALENCY: The Implant Resource Pins and Wires is substantially equivalent to the Zimmer and Depuy Internal Fixation Systems.

SUMMARY OF SAFETY AND EFFECTIVENESS: The Medical Products Resource Pins and Wires Internal Fixation are shown to be safe and effective for temporary use in fracture fixation of broken bones in the human body. Spinal wires have shown to be safe and effective in assisting with straightening of curvatures of the spine.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 11 2000

Mr. Al Lippincott
Consultant
Implant Resource, Inc.
c/o Engineering Consulting Services
3150 East 200th Street
Prior Lake, Minnesota 55372

Re: K002125
Trade Name: Pins and Wires
Regulatory Class: II
Product Codes: HTY
Dated: July 12, 2000
Received: July 14, 2000

Dear Mr. Lippincott:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D. for
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Medical Products Resource mpr™

510(k) NUMBER: K002125

DEVICE NAME: PINS and WIRES

INDICATIONS FOR USE:

Internal fixation pins and wires are temporary appliances and are utilized in skeletal traction for alignment of long bone fractures, as guide wires in hip pinning, and fracture alignment in certain other types of fractures. Spinal wire fixation is for securing hooks, rods, plates to the spinal spinous process in straightening spine curvature disorders.

NRD for cmw

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002125

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use

(Per 21 CFR 801.109) (Optional Format)